

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit:

CHANG ET AL.

Examiner:

APPLICATION NO: TBA (div. of 08/974,391) Atty. Docket: 4-31401A

FILED: Herewith

FOR: VECTORS FOR TISSUE-SPECIFIC REPLICATION AND GENE  
EXPRESSION

Commissioner for Patents  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
MAIL STOP: PATENT APPLICATION

PRELIMINARY AMENDMENT

Sir:

Please cancel claims 1-37 prior to calculating the filing fee in this application.

Remarks

Claims 1-37 in parent application No. 08/974,391, were subject to a restriction/election requirement dated 2/8/99 (copy enclosed) whereby the claims were grouped as follows: Group I – claims 1-19, 25, and 28-29; Group II – claims 20-24 and 26; Group III – claims 30 and 32; Group IV – claims 27, 31, and 33-37. Group I was elected in parent application No. 08/974,391. Claims 38-96 of the instant application correspond to the original Group II claims (20-24 and 26).

Respectfully submitted,



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Date: June 24, 2003



## UNITED STATES DEPARTMENT OF COMMERCE

## Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231-1000 Art Unit

Received 3d. Month

1992

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/974,391	11/19/97	CHANG	

08/974,391 11/19/97 CHANG

1. This action is filed.

HM12/0208

EXAMINER

2. Sole COUNSEL: KESSLER, GOLDSTEIN &amp; FOX formal masters, pro hac vice, 1100 NEW YORK AVENUE, N.W., P.O. 11, 463 O.G. 219

A shorted SUITE 600, WASHINGTON, DC 20005-3934. Failure to respond within the period for response will cause the application to become abandoned (37 CFR 1.136(e)). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

DATE MAILED:

Claims Not Yet Filed

X Claims 1-27

Of the above, claims 1

Claims by

**Please find below and/or attached an Office communication concerning this application or proceeding.**

Claims 1

Claims 1-27

Application Process:

1. See instructions to applicants in the Office's Patent Application Guide, PTO-892.

2. The attorney or agent of record is responsible for this application.

DOCKETED

Restriction/Election

March 10, 1999

Stat Bar: August 10, 1999

is also changing to  
**Commissioner of Patents and Trademarks**  
are subject to restriction or election of inventions.RECEIVED  
FEB - 9 1999KESSELER, GOLDSTEIN & FOX PLLC  
RWE 219 RWS

B.I.D. B.O. 400

Information Disclosure Statement

Information Disclosure Statement (IDS) - 1 of 1 page(s)

Information Disclosure Statement (IDS) - 2 of 1 page(s)

Information Disclosure Statement (IDS) - 3 of 1 page(s)

Information Disclosure Statement (IDS) - 4 of 1 page(s)

## Office Action Summary

Application No. 08/974,391	Applicant(s) Chang et al.
Examiner Karen M. Hauda	Group Art Unit 1632



- Responsive to communication(s) filed on \_\_\_\_\_.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

- Claim(s) 1-37 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) \_\_\_\_\_ is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims 1-37 are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, 25 and 28-29, drawn to a vector comprising a first and second coding sequence, host cells containing the same, and methods of making the same, classified in class 435, subclass 320.1.
- II. Claims 20-24 and 26, drawn to a virion, host cells containing the same, and methods of producing the same, classified in class 435, subclass 456.
- III. Claims 30 and 32, drawn to a method of modulating the replication of a vector, classified in class 435, subclass 375.
- IV. Claims 27, 31 and 33-37, drawn to a method for introducing a vector into a cell in vitro or in vivo, and methods of diagnosing cell replication and treating a tumor in a patient, classified in class 514 or 435, subclass 44 or 69.1, respectively.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Groups III and IV are materially different methods for using the product of Group I,

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such that the product as claimed can be used in a materially different process. Additionally, the vector of Group I can be used as a hybridization probe, for example. The distinction between inventions I and III-IV is further underscored by their divergent subject matter and independent search status.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I and II have different modes of operation, are produced by different reagents and methodologies, and can be used in materially different methods. For example, virions can be used to make producer cells. The distinction between inventions I and II is further underscored by their divergent subject matter and independent search status.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are materially different processes which are not used together. The method of expressing a gene in vitro or in vivo utilizes different strategies, different reagents, and different technical considerations from a method of modulating the replication of a vector. The distinction between inventions III and IV is further underscored by their divergent subject matter and independent search status.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen M. Hauda whose telephone number is (703) 305-6608.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian R. Stanton, may be reached at (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2801.

**The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.**

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Papers related to this application may be submitted to Group 160 by facsimile transmission. Papers should be faxed to Group 160 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is or (703) 305-3014 or (703) 308-4242.

*Karen M. Hauda*  
KAREN HAUDA  
PATENT EXAMINER